

DETAILED ACTION

1. Receipt of the Appeal Brief filed June 11, 2010, is acknowledged and has been entered.
2. Upon further consideration of the record the finality of the rejection of the last Office action is withdrawn in favor of setting forth new grounds of rejection.
3. Claims 29-34 are pending in the application. Claims 31-34 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on April 14, 2009.
4. Claims 29 and 30 are currently under prosecution.

Priority

5. Applicant's claim under 35 U.S.C. §§ 119(e) and/or 120, 121, or 365(c) for benefit of the earlier filing date of Application No. 09/804,690, filed March 12, 2001, which claims benefit of Application No. 09/146,187, filed September 1, 1998, which claims benefit of Application No. 08/977,818, filed November 25, 1997, which claims benefit of Application No. 08/670,274, filed June 13, 1996, which claims benefit of Application No. 08/585,758, filed January 16, 1996, which claims benefit of Provisional Application No. 60/006,856, filed November 16, 1995, is acknowledged.

However, claims 29 and 30 do not properly benefit under §§ 119 and/or 120 by the earlier filing dates of the priority documents claimed, since those claims are rejected under 35 U.S.C. § 112, first paragraph, as lacking adequate written description and a sufficiently enabling disclosure.

To receive benefit of the earlier filing date under §§ 119 and/or 120, the later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional

application); the disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994). See M.P.E.P. § 201.11.

In this instance, the subject matter to which the claims are directed, namely a polypeptide comprising the amino acid sequence of the amino acid sequence spanning positions 11 to 390 of SEQ ID NO: 4, is not described in the preceding applications, *which fail to describe the amino acid sequence of SEQ ID NO: 4*. To be clear, the prior applications set forth and/or describe an amino acid sequence that consists of the amino acid sequence spanning positions 11 to 390 of SEQ ID NO: 4, but none describe the entirety of SEQ ID NO: 4 and none describe the claimed genus of polypeptides comprising the particular fragment of SEQ ID NO: 4 spanning positions 11-390; and accordingly none describe the claimed subject matter.

Accordingly, the effective filing date of the claims is deemed the filing date of the instant application, namely October 29, 2003.

Specification

6. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required:

Claims 29 and 30 are drawn to a polypeptide comprising the amino acid sequence of the amino acid sequence spanning positions 11 to 390 of SEQ ID NO: 4. However, although the Sequence Listing, as originally filed, includes the amino acid sequence of SEQ ID NO: 4 (in its entirety), the specification does not describe a polypeptide having an amino acid sequence consisting of (or comprising) the particularly claimed fragment of the amino acid sequence of SEQ ID NO: 4.

M.P.E.P. § 608.01(o) states:

While an applicant is not limited to the nomenclature used in the application as filed, he or she should make appropriate amendment of the specification whenever this nomenclature is departed from by amendment of the claims so as to have clear support

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or antecedent basis in the specification for the new terms appearing in the claims. This is necessary in order to insure certainty in construing the claims in the light of the specification, *Ex parte Kotler*, 1901 C.D. 62, 95 O.G. 2684 (Comm'r Pat. 1901). See 37 CFR 1.75, MPEP § 608.01(i) and § 1302.01.

M.P.E.P. § 608.01(o) further states that if the examiner determines that the claims presented late in prosecution do not comply with 37 CFR 1.75(d)(1), applicant will be required to make appropriate amendment to the description to provide clear support or antecedent basis for the terms appearing in the claims, provided no new matter is introduced.

It is submitted that it would not be clear from a reading of the descriptive portion of this application, alone, where there is support for the language of the claims because apart from the listing of the amino acid sequence of SEQ ID NO: 4 in the present Sequence Listing, there is no other reference to this sequence in the written portion of the disclosure which describes the claimed polypeptide comprising the amino acid sequence of SEQ ID NO: 4 or the particularly claimed fragment thereof. In fact, while the instant specification describes fragments of the disclosed TSG101 polypeptides, it does not describe fragments of "SEQ ID NO: 4"¹ nor does it describe polypeptides that comprise or consist of any particular portion of SEQ ID NO: 4 (e.g., the claimed portion spanning positions 11-390).

Notably, claims 29 and 30 are not original claims and as such the claims are rejected below as violating the written description requirement set forth under 35 U.S.C. § 112, first paragraph; accordingly, Applicant is advised that this issue cannot be remedied by amending the disclosure to include antecedent basis for the language of the claims without introducing new matter into the disclosure.

Claim Objections

7. Claims 29 and 30 are objected to under 37 CFR 1.75(c), as failing to conform to the invention as set forth in the remainder of the specification, where the terms and phrases used in the claims must find clear support or antecedent basis in the description so that the meaning of the terms in the claims may be ascertainable by reference to the description. See M.P.E.P. § 608.01(g).

There is no written support in the descriptive portion of this application, as originally filed, for the claimed subject matter, namely a polypeptide comprising the amino acid sequence of amino acids 11-390 of SEQ ID NO: 4.

At best, the specification, as originally filed, describes the amino acid sequence of SEQ ID NO: 4. This is because the originally filed specification sets forth SEQ ID

¹ The term "SEQ ID NO: 4" is not found anywhere in the text of the disclosure; moreover, the claimed fragment of the sequence (i.e., amino acids 11-390 of SEQ ID NO: 4) is not described anywhere in the

NO: 4 *in its entirety* in the Sequence Listing (although it is aptly noted that no where in the specification is there a disclosure pertaining to and describing a polypeptide having this particular amino acid sequence) but it does not describe the particular fragment of SEQ ID NO: 4 to which the claims are directed.

Appropriate correction is required (i.e., Applicant should make appropriate amendment to the description to provide clear support or antecedent basis for the terms appearing in the claims, as in accordance with the guidance set forth under M.P.E.P. § 608.01(o)).

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 29 and 30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 29 and 30 are drawn to a polypeptide comprising the sequence of amino acid residues 11-390 of SEQ ID NO: 4.

Claims 29 and 30 are not original claims. Claims 29 and 30 were added by the amendment filed February 26, 2007.

It appears that it is Applicant's position that written support for the language of the claims is found in the disclosures of the prior filed applications to which the present application claims priority.

While the prior applications appear to set forth in their Sequence Listings and/or describe an amino acid sequence consisting of the sequence spanning the amino acids positions 11-390 of SEQ ID NO: 4, none describe SEQ ID NO: 4. SEQ ID NO: 4 is an amino acid sequence of 390 amino acids; but the sequence that is disclosed by the prior applications is not.

Notably, there is an amino acid sequence set forth in the Sequence Listing of the prior applications, which is 380 amino acids in length and which is identical to the amino acid sequence spanning the amino acids at positions 11 and 390 of SEQ ID NO: 4 (as disclosed by the Sequence Listing in the instant application). This amino acid sequence, which is similar but not identical to SEQ ID NO: 4 and which is disclosed by the prior applications is also designated "SEQ ID NO: 4".

For clarity, this application was amended by the preliminary amendment filed on the date the application was filed (i.e., October 29, 2003) to replace the amino acid sequence disclosed by the prior filed applications as SEQ ID NO: 4 with that of the present amino acid sequence also designated SEQ ID NO: 4. As such, the present application describes an amino acid sequence (SEQ ID NO: 4) that is not described by the prior applications and it is to this amino acid sequence to the present claims are now directed. Because the prior applications do not disclose the amino acid sequence to which the present claims are directed, none of the disclosures of the prior applications, if incorporated by reference into the disclosure of this application, serve to describe the claimed subject matter.

Then, because the instant disclosure does not describe a polypeptide comprising the sequence of amino acid residues 11-390 of SEQ ID NO: 4², there is no written support for the language of the claims in the disclosure of the instant application, as originally filed.

For these reasons it is submitted that the addition of claims 29 and 30 by the amendment filed February 26, 2007, introduced new concepts into the specification,

² SEQ ID NO: 4 is set forth in the Sequence Listing, but the text of the disclosure contains no reference to this particular amino acid sequence and fails to describe the claimed polypeptide comprising an amino acid sequence, which is the fragment of SEQ ID NO: 4 spanning the amino acids at positions 11 and 390.

which were not adequately supported by the disclosure, thereby introducing new matter into the specification and violating the written description requirement set forth under 35 U.S.C. § 112, first paragraph.

Given Applicant's comments, which were made at page 6 of the Appeal Brief filed June 11, 2010, it appears that the replacement of SEQ ID NO: 4, as disclosed by the prior applications to which this application claims priority, by the altered amino acid sequence set forth in the instant Sequence Listing may have been an error. So, as was suggested to Applicant's representative during recent interviews, it may be remedial to amend the specification to provide antecedent basis for the language of the original claims drawn to a polypeptide comprising the amino acid sequence of SEQ ID NO: 4 (e.g., claims 26 and 27, which were added by the preliminary amendment filed October 29, 2003), provided Applicant also file a substitute Sequence Listing in which the amino acid sequence listed as SEQ ID NO: 4 is the same as that which is disclosed by the earlier filed parent applications. Once the present Sequence Listing is replaced by a substitute Sequence Listing, which discloses SEQ ID NO: 4 to be that amino acid sequence that is described by SEQ ID NO: 4 in the earlier filed applications, and the instant disclosure is amended to provide written support for the language of the claims, the following new claims should be found allowable over the prior art:

Claim 35. (New) An isolated polypeptide comprising the amino acid sequence of SEQ ID NO: 4.

Claim 36. (New) A polypeptide comprising the amino acid sequence of SEQ ID NO: 4, free of other proteins and cellular debris.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. The rejection of claims 29 and 30 under 35 U.S.C. 102(b), as being anticipated by the disclosure by GENBANK Accession No. U82130.1 (04 June 1998) (of record), is maintained.

Applicant's arguments traversing the propriety of maintaining this ground of rejection have been carefully considered but not found persuasive for the following reasons:

As explained above, claims 29 and 30 do not properly benefit under §§ 119 and/or 120 by the earlier filing dates of the priority documents claimed, since those claims are rejected under 35 U.S.C. § 112, first paragraph, as lacking adequate written description and a sufficiently enabling disclosure.

Again, in order to receive benefit of the earlier filing date under §§ 119 and/or 120, the later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application); the disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994). See M.P.E.P. § 201.11.

In this instance, the subject matter to which the claims are directed, namely a polypeptide comprising the amino acid sequence of the amino acid sequence spanning positions 11 to 390 of SEQ ID NO: 4, is not described in the preceding applications, *which fail to describe the amino acid sequence of SEQ ID NO: 4*. To be clear, the prior applications set forth and/or describe an amino acid sequence that consists of the amino acid sequence spanning positions 11 to 390 of SEQ ID NO: 4, but none describe the entirety of SEQ ID NO: 4 and none describe the claimed genus of polypeptides comprising the particular fragment of SEQ ID NO: 4 spanning positions 11-390; and accordingly none describe the claimed subject matter.

Accordingly, the effective filing date of the claims is deemed the filing date of the instant application, namely October 29, 2003.

GENBANK Accession No. U82130.1 describes the amino acid sequence of SEQ ID NO: 4, which is an amino acid sequence comprising the claimed portion thereof spanning the amino acids at positions 11 to 390.

Although the disclosure does not expressly teach a polypeptide comprising the disclosed amino acid sequence, which is isolated and/or free of other proteins and cellular debris, the artisan of ordinary skill in the relevant art would recognize the claimed polypeptide to be the same as the polypeptide comprising the disclosed amino

acid sequence and thus the limitations are not given patentable weight in distinguishing the claimed polypeptide from that which would be understood to have been disclosed by the prior art. Moreover, it is implicit that the polypeptide described by the prior art, if synthesized in accordance with the factual information disclosed, would in fact be isolated and therefore free of other proteins and cellular debris.

12. Claims 29 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by the disclosure by Li et al. (*Cell*, 1997 Jan 10; 88: 143-154).

Claims 29 and 30 are drawn to an isolated polypeptide comprising the sequence of amino acid residues 11-390 of SEQ ID NO: 4.

As explained, the effective filing date of the claims is deemed the filing date of the instant application, namely October 29, 2003.

Li et al. teaches an isolated polypeptide comprising the sequence of amino acid residues 11-390 of SEQ ID NO: 4; see entire document (e.g., page 144, Figure 1B).

13. Claims 29 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by the disclosure by U.S. Patent No. 6,586,185.

Claims 29 and 30 are drawn to an isolated polypeptide comprising the sequence of amino acid residues 11-390 of SEQ ID NO: 4.

As explained, the effective filing date of the claims is deemed the filing date of the instant application, namely October 29, 2003.

U.S. Patent No. 6,586,185 (Wolf et al.) teaches an isolated polypeptide comprising the sequence of amino acid residues 11-390 of SEQ ID NO: 4; see entire document (e.g., SEQ ID NO: 2).

Conclusion

14. No claim is allowed.

15. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure. Each of U.S. Patent Nos. 6,812,339, 5,892,016, and 6,472,508

teaches an isolated polypeptide comprising the sequence of amino acid residues 11-390 of SEQ ID NO: 4.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings whose telephone number is (571) 272-0836. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Misook Yu can be reached on (571) 272-0839. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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